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| 09/924,156 | 08/07/2001 | Rafael A. Sierra | 11325-84822 | 1453 |

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| EXAMINER | |
|---|---|
| FARAH, AHMED M | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 3739 | |

DATE MAILED: 10/03/2003

11

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

| Application No. | Applicant(s) |
|---|---|
| 09/924,156 | Sierra et al. |
| **Examiner** | **Art Unit** |
| Ahmed M. Farah | 3739 |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *three* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1) ☐ Responsive to communication(s) filed on _____.

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

**Disposition of Claims**

4) ☒ Claim(s) *1-19* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *1-19* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

**Application Papers**

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 7
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

## DETAILED ACTION

### *Oath/Declaration*

1. The auth/declaration is not signed by all applicants. However, the examiner notes that a petition under 37 CFR 1.47(a) has been granted on November 13, 2002 (Paper No. 10)

### *Claim Objections*

2. Claim 16 is objected to because of the following informalities: the recitation "said step" in line 1 lacks proper antecedence in the parent claim 15. Examiner suggests that either the phrase --steps of-- inserted after the word "comprising" in the preamble of claim 15, or the recitation "said step" removed from the claim. Appropriate correction is required.

### *Claim Rejections - 35 USC § 112*

3.The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claim 19 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5. Claim 19 recites the limitation "said glycolic acid" in line 1. There is insufficient antecedent basis for this limitation in the claim.

***Claim Rejections - 35 USC § 102***

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claims 1-15 are rejected under 35 U.S.C. 102(e) as being anticipated by Anderson U.S. Patent No. 6,600,951 B1.

With respect to claims 1, 7, 11, and 15, *Anderson* '951 discloses methods for treating skin conditions associated with the production of sebum (methods for treating sebaceous gland disorders, see the abstract), comprising the steps of: introducing an exogenous chromophore to sebaceous glands; and irradiating the target sebaceous glands with laser light having a sufficient energy and fluence to disrupt the functions of the sebaceous glands as presently claimed:

> The present invention is based, at least in part, on the discovery that energy activatable materials, such as chromophores, described infra, in combination with an energy source, e.g., photo (light) therapy, can be used to treat sebaceous gland disorders, e.g., eliminate, inhibit, or prevent occurrence or reoccurrence of the skin disorder.

> A preferred example of such a sebaceous gland disorder is acne.
>
> The present invention pertains to methods for treating skin disorders associated with sebaceous follicles by **topically applying** an energy activatable material to a section of skin afflicted with a sebaceous gland disorder, wherein the material is activated by energy which penetrates outer layers of epidermis. A sufficient amount of the material infiltrates the afflicted section of skin and is exposed to sufficient energy to cause the material to become photochemically or photothermally activated, thereby treating the sebaceous gland disorder. In one embodiment, the sebaceous gland disorder is acne.

*Anderson* '951, column 1, line 61 to column 2, line 11. As to the wavelength recitation in claims 1 and 15, *Anderson* teaches the preferred wavelength for the treatment is between 600-1200 nm:

> It is highly preferred to use wavelengths of the optical spectrum in which natural skin pigments exhibit weaker absorption (to minimize heating at other sites), and which penetrate well to the anatomic depth of the infundibulum and/or sebaceous glands. The orange, red, and near-infrared wavelength region (600-1200 nm) is therefore most appropriate.

*Anderson* '951, column 7, line 66 to column 8, line 5. Hence, the wavelength range of *Anderson* embraces and/or overlaps the wavelength range recited in the claims. As to the recitation in claim 15 that 'the target skin is cleaned in a manner to clear the pores,' Anderson teaches the target skin is substantially cleaned :

> Generally, the site of treatment and a major muscle site are cleansed with an alcoholic solution.
>
> ...reactive byproducts can interact with the localized surrounding tissue area such that the tissue is cleansed of unwanted material, e.g., oils, bacteria, viruses, dirt, etc.

*Anderson* '951, column 15, lines 54-56, and column 6, lines 37-39. Hence, *Anderson* teaches the step of cleaning the target skin as recited in the claim.

With respect to claims 2, 4, 8, and 12, *Anderson* '951 teaches that a chromophore in a lipid suspension is topically applied onto the skin:

> In a one embodiment, liposomes are used to deliver the energy activatable material to the follicle matrix. Liposomes provide site-specific transdermal delivery to the follicle matrix. In this embodiment, the energy activatable material is microencapsulated within the liposome and topically applied to the epidermis of the skin. ...
>
> These liposomal compositions are topically applied to the skin and deliver the encapsulated energy activatable material to the follicle region including the sebaceous gland and infundibulum. ...
>
> The liposomes may be made from natural and synthetic phospholipids, and glycolipids and other **lipids and lipid** congeners; cholesterol, cholesterol derivatives and other cholesterol congeners; charged species which impart a net charge to the membrane; reactive species which can react after liposome formation to link additional molecules to the lysome membrane; and other lipid soluble compounds which have chemical or biological activities.

*Anderson* '951, column 12, line 57 to column 13, line 25. Hence, Anderson anticipates the recited limitations.

With respect to claim 3, *Anderson* '951 teaches that the lipid suspension comprises a water, a pharmaceutical acceptable oil, and at least one surfactant:

> Liquid dosage forms for topical administration of the compounds of the invention include pharmaceutically acceptable emulsions, microemulsions, solutions, creams, lotions, ointments, suspensions and syrups.

> The term "cream" is art recognized and is intended to include semi-solid emulsion systems which contain both an oil and water. Oil in water creams are water miscible and are well absorbed into the skin, Aqueous Cream BP. Water in oil (oily) creams are immiscible with water and, therefore, more difficult to remove from the skin. These creams are emollients, lubricate and moisturize, e.g., Oily Cream BP. Both systems require the addition of either a natural or a synthetic **surfactant** or emulsifier.

*Anderson* '951, column 12, lines 3-6, and column 12, lines 29-37. Hence, *Anderson* anticipates the lipid suspension comprises a water, a pharmaceutical acceptable oil, and at least one surfactant recited in the claim.

With respect to claims 5 and 6, *Anderson* '951 teaches the chromophore is selected from the group consisting a dye such as indocyanine green:.

> Preferred energy activatable materials include laser sensitive dyes, for example, methylene blue, indocyanine green and those in U.S. Pat. No. 4,651,739, issued Mar. 24, 1987, the entire contents of which are incorporated herein by reference.
>
> Delivery of the energy activatable material, preferably methylene blue or other FDA approved dyes, to the follicle matrix can be achieved by topical application, injection, liposome encapsulation technology, massage, iontophoresis or ultrasonic technology, or other means for delivery of compounds into the dermal region of the skin, e.g., pharmaceutically acceptable carriers.

*Anderson* '951, column 5, line 67 to column 6, line 4; and column 11, lines 27-33, respectively.

With respect to claims 13 and 14, *Anderson* '951 teaches that the chromophore is topically delivered to the target site through a solubilizing carrier selected from the group consisting of sunflower oil, olive oil, and safflower oil:

> a pharmaceutically acceptable material, composition or vehicle, such as a liquid or solid filler, diluent, excipient, solvent or encapsulating material, involved in carrying or transporting a energy activatable material of the present invention within or to the subject ..... some examples of materials which can serve as pharmaceutically acceptable carriers include: ... oils, such as peanut oil, cottonseed oil, safflower oil, sesame oil, olive oil, corn oil and soybean oil;... Preferred carriers include those which are capable of entering a pore by surface action and solvent transport such that the energy activatable material is carried into or about the pore, e.g., into the sebaceous gland, to the plug, into the infundibulum and/or into the sebaceous gland and infundibulum.

*Anderson* '951, column 11, lines 35-64. Hence, *Anderson* anticipates the recited limitations.

With respect to claims 9 and 10, *Anderson* '951 teaches the suitable laser source is selected from the group consisting of an Nd:YAG, alexandrite, flashlamp-pumped, and diode lasers. He further teaches the suitable pulse duration of 0.1-100 msec and fluence of about 5-100 J/cm$^2$:

> Suitable energy sources include flash lamp based sources and lasers, such as Nd: YAG, Alexandrite, flash lamp-pumped dyes and diodes.
>
> ...the preferred range of pulse duration is 0.1-100 ms, and the ideal pulse duration is about 10-50 ms.
>
> The tolerable fluence for human skin of an optical pulse in this part of the spectrum is about 5-100 J/cm.sup.2, depending on the amount of epidermal melanin and on wavelength.

*Anderson* '951, column 2, lines 11-13; column 7, lines 59-61; and column 8, lines 14-17. Hence, *Anderson* anticipates the use of diode laser, a pulse duration of about 1-100 msec, and a fluence of about 5-40 J/cm$^2$ as recited in the claims.

***Claim Rejections - 35 USC § 103***

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. Claims 16-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over *Anderson* '951 in view of Albacarys et al. U. S. Patent No. 6,338,855 B1.

Although, *Anderson* '951, described above, teaches a method for cleaning the target skin with or without solvent (column, 14, lines 61-63), he does not particularly teach the use of glycolic acid solution mixed with a neutralizing agent such as water, bicarbonate, or glytone.

However, Albacarys et al. teach a solution and method for cleaning skin tissue including acne, the skin cleansing solution including a water soluble glycolic acid solution:

> Nonlimiting examples of conditioning agents useful as water soluble conditioning agents include those selected from the group consisting of ... Specific examples of useful water soluble conditioning agents include materials such as urea; guanidine; glycolic acid and glycolate salts.
>
> The present invention also relates to a method of cleansing and treating the skin or hair with a personal cleansing article of the present invention. These methods comprise the steps of wetting with water a substantially dry, disposable, single use personal cleansing article comprising a water insoluble substrate, a lathering surfactant, and a skin care active component, and contacting the skin or hair with such wetted article.

Albacarys et al. '855, column 41, lines 47-59; column 50, lines 46-53. Also, see the abstract; column 17, lines 15 to column 18, line 17; and column 25, line 50 to column 26, line 18;.

Therefore, it would have been obvious to one skilled in the art at the time of the applicant's invention to modify Anderson in view of Albacarys et al. and use a water and/or water soluble glycolic acid solution in order to clean the target site. This would enhance the treatment by first cleaning the target from unwanted material such as skin oil, dirt, etc. and removing access photosensitive chromophores from the skin area to reduce/eleminate damage to the untargeted surrounding tissues.

***Conclusion***

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. See the following references:

U.S. Patent No. 6,235,016 to Stewart; U.S. Patent No. 6,183,773 B1. to Anderson; and U.S. Patent No. 6,036,684 to Tankovich et al. disclose various methods for reducing sebum production by altering the functions of sebaceous glands using optical energies. Their treatment methods are suitable for treating acne.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to A. Farah whose telephone number is (703) 305-5787. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak, can be

reached on (703) 308-0994. The official fax number for the group is (703) 872-9302; the fax number for After Final is (703) 872-9303; and the Examiner's Desk-top fax is (703) 746-3368.

**A. M. Farah**

**Patent Examiner** (Art Unit 3739)

September 25, 2003.